

5. 510(k) SUMMARY

JUL 31 2007

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, CA 92121
Telephone: (858) 909-1868
Date Prepared: January 12, 2007.

B. Device Name

Trade or Proprietary Name:	<i>Graft Containment Device</i>
Common or Usual Name:	Graft Containment Device
Classification Name:	Appliance, Fixation, Spinal Intervertebral body, code KWQ.

C. Predicate Devices

The subject device is substantially equivalent to similar previously cleared devices.

D. Device Description

The *Graft Containment Device* consists of a series of specialized shapes of surgical mesh made from commercially available polyester suture fibers. All sizes incorporate regions of reinforced holes to assist secure anchoring of the mesh to tissue. The devices are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

Bone screws intended for anchoring the graft containment device to bone, and made from PEEK, carbon-fiber reinforced PEEK, or titanium are also available.

E. Intended Use

The Graft Containment Device, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.

Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests

(Not Applicable).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NuVasive, Incorporated
% Ms. Laetitia Cousin
Director of Regulatory Affairs
and Quality Assurance
4545 Towne Centre Court
San Diego, California 92121

JUL 31 2007

Re: K070148
Trade/Device Name: Graft Containment Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 14, 2007
Received: June 15, 2007

Dear Ms. Cousin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

4. INDICATIONS FOR USE510(k) Number (if known): K070148Device Name: Graft Containment Device

Indications for Use:

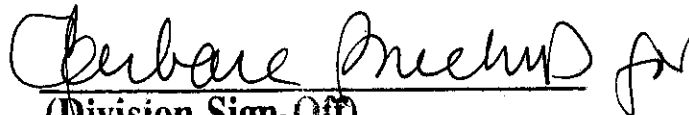
The Graft Containment Device, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)**Division of General, Restorative,
and Neurological Devices**510(k) Number K070148